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Name of Person Signing Certificate: Mary Mitchell

April 5, 2004
Date

Mary Mitchell
Signature

MAIL STOP AF

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Applicant:	§	**Confirmation No.:**	**4672**
CHAOYING ZHAO	§		
Filed: November 15, 2000	§	Art Unit:	1616
Serial No.: 09/713,498	§	Examiner:	John D. Pak
For: NOVEL PHARMACEUTICAL COMPOSITIONS FOR TREATING AND SAVING AND THE PREPARATION THEREOF	§	Docket No.:	014938.0003
	§	Customer No.:	01200

TRANSMITTAL OF APPEAL BRIEF

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Transmitted herewith is Appellant's Brief in triplicate in support of the above-identified application.

A check in the amount of $165.00 is enclosed to cover the filing fee of the Brief. The Commissioner is hereby authorized to charge any additional fees which may be required or credit overpayment to Deposit Account No. 16-2435. A duplicate of this sheet is enclosed.

Respectfully submitted,

Charles M. Cox

Charles M. Cox, Reg. No. 29,057
ATTORNEY OR AGENT OF RECORD

Date: April 5, 2004

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PTO/SB/17 (01-03)

FEE TRANSMITTAL for FY 2003

Patent fees are subject to annual revision

Total Amount of Payment	$ 165.00

Complete if Known	
Application Number	09/713,498
Filing Date	November 15, 2000
First Named Inventor	CHAOYING ZHAO
Examiner Name	John D. Pak
Group / Art Unit	1616
Attorney Docket No.	014938.0003

METHOD OF PAYMENT (check one)

1. ___ The Commissioner is hereby authorized to charge indicated fees and credit any overpayments to:
   Deposit Account No.: 16-2435
   Deposit Account Name: Akin, Gump, Strauss, Hauer & Feld, L.L.P.
   _X_ Charge any additional Fee Required Under 37 CFR §§ 1.16 & 1.17
   _X_ Applicant claims small entity status. See 37 CFR 1.27
2. ___ Payment Enclosed: ___ Check ___ Money Order ___ Credit Card ___ Other

FEE CALCULATION

1. Basic Filing Fee

Large Fee Code	Large Entity Fee ($)	Small Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
1001	$750	2001	$375	Utility Filing Fee	$
1002	$330	2002	$165	Design Filing Fee	$
1003	$520	2003	$260	Plant Filing Fee	$
1004	$750	2004	$375	Reissue Filing Fee	$
1005	$160	2005	$ 80	Provisional Filing Fee	$
				Subtotal (1)	$

2. Extra Claim Fees

Claims		Extra		Fee (below)		Fee Paid
Total	__ -20** =		x	$	=	$
Indep.	__ - 3** =		x	$	=	$
Multiple Dependent						$

**or number previously paid, if greater.

For Reissues, see below

Large Entity Fee ($)	Small Entity Fee ($)	Fee Description
$	$	Claims in excess of 20
$	$	Independent claims in excess of 3
$	$	Multiple dependent claim, if not paid
$	$	**Reissue independent claims over original patent
$	$	**Reissue claims in excess of 20 and over original patent
	Subtotal (2)	$

FEE CALCULATION (continued)

3. Additional Fees

Large Fee Code	Large Entity	Small Fee Code	Small Entity	Fee Description	Fee Paid
1051	$ 130	2051	$ 65	Surcharge - late fee or oath	$
1052	$ 50	2052	$ 25	Surcharge - late provisional filing fee or cover sheet	$
1812	$2,520	1812	$2,520	Request for Reexamination	$
1804	$920*	1804	$920*	Requesting publication of SIR prior to Examiner action	$
1805	$1840*	1805	$1840*	Requesting publication of SIR after Examiner action	$
1251	$ 110	2251	$ 55	Extension for reply within first month	$
1252	$ 410	2252	$ 205	Extension for reply within second month	$
1253	$ 930	2253	$ 465	Extension for reply within third month	$
1254	$1,450	2254	$ 725	Extension for reply within fourth month	$
1255	$1,970	2255	$ 985	Extension for reply within fifth month	$
1401	$ 320	2401	$ 160	Notice of Appeal	$
1402	$ 320	2402	$ 160	Filing a brief in support of an appeal	$ 165.00
1403	$ 280	2403	$ 140	Request for oral hearing	$
1452	$ 110	2452	$ 55	Petition to revive - unavoidable	$
1453	$1,300	2453	$ 650	Petition to revive - unintentional	$
1501	$1,300	2501	$ 650	Utility issue fee (or reissue)	$
1502	$ 470	2502	$ 235	Design issue fee	$
1503	$ 630	2503	$ 315	Plant issue fee	$
1460	$ 130	1460	$ 130	Petitions to the Commissioner	$
1807	$ 50	1807	$ 50	Petitions related to provisional applications	$
1806	$ 180	1806	$ 180	Submission of Information Disclosure Statement	$
8021	$ 40	8021	$ 40	Recording each patent assignment per property (times number of properties)	$
1809	$ 750	2809	$ 375	Filing a submission after final rejection (37 CFR 1.129(a))	$
1801	$ 750	2801	$ 375	Request for Continued Examination (RCE)	$
1802	$ 900	1802	$ 900	Request for expedited examination of a design application	$

Other fee (specify): _____ $

Other fee (specify): _____ $

* Reduced by Basic Filing Fee Paid

Subtotal (3) $ 165.00

Date: April 5, 2004

Submitted by

Charles M. Cox

Charles M. Cox, Reg. No. 29,057

CERTIFICATE OF MAILING 37 C.F.R. 1.8(a)

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date indicated below.

Name of Person Signing Certificate: Mary Mitchell

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Mary Mitchell
Signature

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Applicant:		§		
	CHAOYING ZHAO	§		
Filed:	November 15, 2000	§	Art Unit:	1616
Serial No.:	09/713,498	§	Examiner:	John D. Pak
For:	NOVEL PHARMACEUTICAL COMPOSITIONS FOR TREATING AND SAVING AND THE METHOD FOR PREPARATION THEREOF	§	Docket No.:	014938.0003
		§	Customer No.:	20594

APPEAL BRIEF

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TABLE OF CONTENTS

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re:	Patent Application of CHAOYING ZHAO	: Group Art Unit: 1616
Appln. No.:	09/713,498	: Examiner: John D. Pak
Filed:	November 15, 2000	:
For:	NOVEL PHARMACEUTICAL COMPOSITIONS FOR TREATING AND SAVING AND THE METHOD FOR PREPARATION THEREOF	: Attorney Docket: 014938.0003

Mail Stop Appeal Brief – Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

APPELLANT'S BRIEF

This brief is in furtherance of a Notice of Appeal, filed in this case on February 4, 2004.

The fees required under § 1.17 are dealt with in an accompanying letter of TRANSMITTAL OF APPEAL BRIEF.

This brief is transmitted in triplicate.

The final page of this brief bears the practitioner's signature.

I. REAL PARTY OF INTEREST

The real party in interest in this appeal is the party named in the caption of this brief.

II. RELATED APPEALS AND INTERFERENCES

There are no appeals or interferences that will directly affect, or be directly affected by, or have a bearing on the Board's decision in this appeal.

III. STATUS OF CLAIMS

The status of the claims in this application are:

1. Claims cancelled: 1-19

2. Claims 23-24, 26, 29 and 31-36, withdrawn as directed to non-elected subject matter, have been cancelled.

3. Claims 20-22, 25-28, and 30 are pending and stand rejected under 35 U.S.C. § 103(a).

The claims on appeal are: 20-22, 25-28, and 30.

IV. STATUS OF AMENDMENTS

No amendment subsequent to the Final Rejection was filed.

V. SUMMARY OF THE INVENTION

Hereafter reference will be made to the Substitute Specification mailed on June 26, 2002 and received by the PTO on July 2, 2002.

This invention is a pharmaceutical composition for the liquid therapy treatment of a patient experiencing traumatic shock to reverse the physiopathological condition of shock (page 1, lines 14-16, ¶ 0001; page 3, lines 26-27; ¶ 0010; page 4, lines 10-11, ¶ 0013). With reference to the species elected for examination (i.e., NaCl + hydroxyethyl starch + injection), in its broadest aspect the claimed pharmaceutical composition contains 1.5–6.9% (w/v) of sodium chloride (NaCl), 3-18% (w/v) of hydroxyethyl starch (HES) and/or as a balance another collid, the balance being an injection liquid, wherein the total sodium ion (Na+) concentration does not exceed an equivalent sodium ion (Na+) concentration of a 6.9% (w/v) NaCl solution (page 15, line 15 – page 6, line 1, ¶ 0015; Claim 20).

Preferred compositions of the invention consist of 4.2 $\pm$ 0.2g NaCl and 7.6 $\pm$ 0.6g HES per 100 ml of injection (page 6, lines 4-6, ¶ 0017, Claims 21 and 30; Example 1).

The invention composition stands in contrast to a 7.5% (w/v) hypertonic NaCl solution heretofore suggested by Velasco for anti-shock therapy. Conventional 7.5% (w/v) NaCl solutions have some toxicity to the organism and can lead to complications such as rupture of blood cells, cardiac insufficiency, decreased renal function and disorders of the nervous system (page 3, line 17-25, ¶ 0008-0009). Here Example (1 page 8, line 12 – page 9, line 1, ¶ 0025-0026) illustrates a preferred pharmaceutical composition of the invention as used in animal studies (page 11, line 27 – page 14, ¶ 0040-0043 and tables) and studies on human patients (page 15, lines 1-8, ¶ 0044). As compared with the prior art, the invention is more effective in

raising blood pressure, increasing urine volume and raising the temperature of the limbs of a subject experiencing shock. The compositions of the invention are useful in greatly decreased volumes of transfusion compared to the prior art, in general the dose for most patients is 500 ml or less (page 15, line 23 – page 16, line 2, ¶ 0048), are rapidly effective, in 5-10 minutes (page 16, lines 1-2, ¶ 0049) and improve the hemodynamics of a subject over a sustained period, 3-4 hours (page 16, lines 13-16, ¶ 0051).

VI. ISSUES

1. Is a pharmaceutical composition "consisting essential of" (1) sodium chloride (NaCl) in an amount of 1.5-6.9% (w/v), (2) hydroxyethyl starch (HES) in an amount of 3-18% (w/v), and (3) an injection, and wherein total sodium ion (Na+) concentration does not exceed that of a 6.9% (w/v) sodium chloride solution, obvious from a hypertonic composition containing (1') NaCl in an amount from 6-8% (w/v), (2') hetastrach (HES) in an amount of 5-25% (w/v), (3') an injection, and (4) L-arginine in an amount of 0.3-7.5% (w/v)?

2. Is a pharmaceutical composition "consisting essential of" (1) sodium chloride (NaCl) in an amount of 4.0-4.4 g/100 ml, (2) hydroxyethyl starch (HES) in an amount of 7.0-8.2 g/100 ml, and (3) an injection, and wherein total sodium ion (Na+) concentration does not exceed that of a 6.9% (w/v) sodium chloride solution, obvious from a hypertonic composition containing (1') NaCl in an amount from 6-8% (w/v), (2') hetastrach (HES) in an amount of 5-25% (w/v), (3') an injection, and (4) L-arginine in an amount of 0.3-7.5% (w/v)?

3. Is a pharmaceutical composition "consisting essential of" (1) sodium chloride (NaCl) in an amount of 1.5 g (g/100 ml), (2) hydroxyethyl starch (HES) in an amount of 3 g (g/100 ml) and dextran 9 g (g/100 ml), and (3) an injection, and wherein total sodium ion (Na+) concentration does not exceed that of a 6.9% (w/v) sodium chloride solution, obvious from a hypertonic composition containing (1') NaCl in an amount from 6-8% (w/v), (2') hetastrach (HES) in an amount of 5-25% (w/v), (3') an injection, and (4) L-arginine in an amount of 0.3-7.5% (w/v)?

4. Is there any disclosure or suggestion in WO98/08500 that when a HES is utilized in a hypertonic NaCl solution that at least 10% of such HES should have a molecular weight of 25,000-45,000 atomic mass units?

5. Is a method for preparing a pharmaceutical composition "consisting essential of" (1) sodium chloride (NaCl) in an amount of 1.5-6.9% (w/v), (2) hydroxyethyl starch (HES) in an amount of 3-18% (w/v), and (3) an injection, and wherein total sodium ion (Na^+) concentration does not exceed that of a 6.9% (w/v) sodium chloride solution, obvious from a hypertonic composition containing (1') NaCl in an amount from 6-8% (w/v), (2') hetastrach (HES) in an amount of 5-25% (w/v), (3') an injection, and (4) L-arginine in an amount of 0.3-7.5% (w/v)?

VII. GROUPING OF CLAIMS

For purposes of Issue No. 1, all of claims 20-22, 25, 27-28 and 30 stand together if Issue No. 1 is answered in the negative, but if Issue No. 1 is answered in the affirmative such that clim 20 falls then nevertheless claims 21-22, 25, 27-28 and 30 do not fall with claim 20.

For purposes of Issue No.2 claims 21 and 30 stand or fall together.

For purposes of Issue No.3 claim 28 stands or falls on its own.

For purposes of Issue No.4 claim 22 stands or falls on its own.

For purposes of Issue No.5 claims 25 and 27 stand or fall together.

VIII. ARGUMENTS

The Rejection

Claims 20-22, 25, 27-28 and 30 stand rejected under 35 U.S.C.§ 103(a) as being unpatentable over WO 98/08500.

The Art Applied For Rejection

WO 98/08500 discloses a hypertonic composition containing L-arginine in addition to sodium chloride as low as 6% (w/v) [page 5, lines 14-15, claim 14], hetastrach (hydroxyl ethyl starch) and, of course, the injection liquid [page 4, line 22].

In the compositions of WO 98/08500 the L-arginine is present in the range of 0.3 to 7.5 g/100ml. The compositions of WO 98/08500 are, because of the presence of L-arginine, said

to be superior to hypertonic saline solutions (7.2 to 7.5% NaCl w/v) and a 7.5% hypertonic saline 6% dextran solution [page 7, lines 11-page 8, line 2] for the treatment of traumatic brain injury (TBI) and hypotension (shock). The L-arginine solutions of WO 98/08500 are designed for the treatment of a patient having the combined injury of TBI and hemorrhage. TBI releases neuroexcitatory amines which increase the oxygen needs of the brain, while tissue swelling and intracranial hemorrhage increases the intracranial pressure (ICP) which reduces cerebral blood flow (CBF). WO 98/08500 further notes that hypotension or reduced mean arterial pressure (MAP) further reduces brain CBF. (WO 1/29 – 2/5). Accordingly, WO 98/08500 sought a composition, that for a patient with combined TBI and hemorrhage, which would, ideally, lower the ICP, selectively vasodilate the brain (but not other vessels of the body), and correct and prevent hypotension and hemorrhagic shock.

WO 98/08500 achieved its invention by adding to a NaCl hypertonic solution (NaCl 6-8g/100ml) L-arginine in a range of 0.3-7.5g/100mo (4/9-11; 5/12-15). This WO 98/08500 did to achieve reduction of ICP and vasodilate the brain even though, L-arginine being a NO generation source, the addition of L-arginine would be expected to reduce to hypertonic saline solution's effectiveness for the correction and prevention of hypotension and hemorrhagic shock.

Hence, as can be seen from the description of WO 98/08500, because L-arginine is converted by NO synthase, an enzyme in brain and blood vessels, into NO which is a potent vasodilator (page 11, Lines 21-24), L-arginine would be expected to lower the ability of a hypertonic saline solution to elevated the blood pressure in a patient experiencing hypotensive shock (page 3, line 30-page 4, line 2). Hence, this blood pressure lowering effect of L'arginine would seem to dictate a need to increase the NaCl content of the hypertonic saline solution to which it is added.

In any event, it is evident from WO 98/08500 that L-arginine materially affects the basic characteristics of a hypertonic saline solution, *i.e.*, namely, the blood pressure elevating property of the hypertonic saline solution.

The Claimed Invention

The invention here involved and claimed is an improved hypertonic saline (NaCl) solution, wherein the improvement comprises limiting the maximum of free sodium ion in the solution to not greater than that of a 6.9% (w/v) NaCl solution.

In this invention, the content of free sodium ion in a hypertonic saline solution is reduced so as to lessen toxicity to the organism, and to reduce the rupture of blood cells and other side effects, while maintaining and/or enhancing its ability to increase the blood pressure of a person in shock by employing hydroxyethyl starch in conjunction with NaCl and generally in greater amounts than NaCl.

WO 98/08500 is willing to suffer the negative effects of L-arginine upon the blood pressure elevating properties of a hypertonic saline-hydroxyethyl starch solution for the correction of hypotension and hemorrhagic shock in order to secure the beneficial effects that L-arginines exerts upon the cerebral blood flow (CBE) and infracranial pressure (ICP) in the case of TBI. Nevertheless, it is evident that inclusion of L-arginine would materially affect the novel and basic characteristics of a hypertonic saline-hydroxyethyl starch composition which applicant here claims.

Issue No. 1

The Examiner has rejected all claims under 35 U.S.C. § 103(a) on grounds "that the consisting essentially of language does not preclude the instant claims from containing L-arginine," this because the Examiner, without any evidentiary support, supposes that "L-arginine would not materially affect the novel and basic characteristics of applicant's invention."

Applicant, for reasons previously advanced, respectfully submits that inclusion of L-arginine in the claimed compositions would materially affect their novel and basic characteristics – *i.e.*, reduce their blood pressure restoring ability since L-arginine is a producer of the potent vasodilator NO.

Accordingly, as was the question in the case of Ex parte Davis, 80 USPQ 448, 450 (Bd Pat App & Int 1949), namely

> "In the present case where the claims recite three ingredients and the reference discloses four, the important question is whether the term "consisting essentially of" excludes that fourth ingredient. "

so too it is the question here. And as in Davis, the answer should "that it does." It does since the L-arginine materially changes the fundamental character of the three-ingredient (NaCl, hydroxyethyl starch, injection) composition claims.

Accordingly, the rejection of all claims in Group 1 should be reversed.

Issue No. 2

The claims of Group 2 further limit the content of NaCl in the claimed solution to within a range of 4.0-4.4 g/100 ml and require an elevated content of HES of 7.0 to 8.2 g/ 100 ml.

Accordingly, even were these "consisting essential of" claims readable upon a L-arginine containing composition, the WO 98/08500 compositions do not describe or suggest a composition of such reduced NaCl concentration. No does WO 98/08500 illustrate a composition wherein the HES concentration of the solution exceeds that of the concentration of NaCl.

Accordingly, the rejection of claims 21 and 30 as obvious over WO 98/08500 should be reversed.

Issue No. 3

The claim of Group 3 further limit the content of NaCl in the claimed solution to 1.5g (g/100 ml) and require a content of HES of 3g (g/ 100 ml), 9 g dextran (g/100 ml), 3.4g of sodium bicarbonate (g/100 ml) and the injection.

Accordingly, even were these "consisting essential of" claims readable upon a L-arginine containing composition, the WO 98/08500 compositions do not describe or suggest a composition of such reduced NaCl concentration.

Accordingly, the rejection of claim 28 as obvious over WO 98/08500 should be reversed.

Issue No. 4

There is no disclosure or suggestion in WO98/08500 that when a HES is utilized in a hypertonic NaCl solution that at least 10% of such HES should have a molecular weight of 25,000-45,000 atomic mass units. The Examiner has cited no evidence to establish that "well known, physiologically acceptable hydroxyethyl starch" has at least 10 % of its content in a molecular weight range of 25,000 – 45,000 atomic mass units. Claim 22 requires at least 10 % of the HES to have a molecular weight of 25,000 – 45,000 atomic mass units. There being no evidence that this characteristic is obvious for a HES used in a hypertonic NaCl solution, claim 22 can not be properly reject on the unsupported assertion by the Examiner. The rejection of claim 22 as obvious over WO 98/08500 should be revered.

Issue No. 5

Since the pharmaceutical composition prepared by the method set forth by the method claims of group 5 is not obvious from WO 98/08500, the method of its preparation is not obvious from WO 98/08500.

IX. APPENDIX OF CLAIMS

The text of the claims involved in the appeal are as follows:

20. A pharmaceutical composition consisting essentially of:

a first substance comprising sodium chloride in an amount between about 1.5% and 6.9% (w/v);

a second substance comprising at least one of hydroxyethyl starch, dextran, carboxymethyl starch, polyvinyl pyrrolidone (PVP), gelatin derivatives, condensed glucose, glucose, fructose, lactose, glycerin, xylitol, sodium alginate, N-2-hydroxypropylacrylamide, ethylene epoxide, polypropylene glycol, pectin, and pentahydroxyethyl starch, wherein said second substance is present in an amount between about 3 and 18 % total (w/v);

a third substance comprising at least one of sodium bicarbonate, potassium chloride, magnesium sulfate, calcium chloride, calcium gluconate, calcium lactate, sodium lactate, sodium acetate and Tris (Hydroxy methyl) aminomethane, wherein said third substance is present in an amount between about 0 and 5.4 % total (w/v); and

an injection comprising at least one of water, physiological saline, balanced buffers, glucose solution, sodium lactate solution, sodium acetate solution, Tris solution, and glucose and sodium chloride solution, wherein said injection is present in an amount between about 75.1% and 95.5% total (w/v),

wherein the total sodium ion concentration does not exceed an equivalent sodium ion concentration of 6.9 % (w/v) sodium chloride solution..

21. The pharmaceutical composition of Claim 20, wherein

said first substance comprises sodium chloride in an amount between about 4.0 and about 4.4 g per 100 ml; and

said second substance comprises hydroxyethyl starch in an amount between about 7.0 g and about 8.2 g per 100 ml.

22. The pharmaceutical composition of Claim 20, wherein said second substance comprises hydroxyethyl starch, at least 10% of which has a molecular weight of about 25,000-45,000 atomic mass units.

25. A method for preparing the pharmaceutical composition of Claim 20, comprising:

dissolving an amount between about 3 g and 18 g of said second substance in a total of 100 ml of said injection;

adding 1.5 g of said first substance; and

mixing said injection to dissolve said first and second substances therein.

27. The method for preparing the pharmaceutical composition of Claim 20 comprising:

dissolving an amount between about 3 g and 18 g of said second substance in a total of 100 ml of said injection;

adding 1.5 g of said first substance;

adding an amount between 0 and about 5.4 g of said third substance, such that the total sodium ion concentration based on said first, second and third substances does not exceed an equivalent sodium ion concentration in a 6.9 % (w/v) sodium chloride solution; and

mixing said injection to dissolve said first, second, and third substances therein.

28. The pharmaceutical composition of Claim 20, wherein

said first substance comprises sodium chloride in an amount of about 1.5 g;

said second substance comprises hydroxyethyl starch in an amount of about 3 g and dextran in an amount of about 9 g;

said third substance comprises sodium bicarbonate in an amount of about 3.4 g; and

said injection comprises physiological saline.

30. The pharmaceutical composition of Claim ~~26~~ 20, wherein

said first substance comprises sodium chloride in an amount of about ~~2.7~~ 4.2 g;

said second substance comprises hydroxyethyl starch in an amount of about 7.6 g; and

said injection comprises water.

If any applicable fee or refund has been overlooked, the Commissioner is hereby authorized to charge any fee or credit any refund to the deposit account of Akin, Gump, Strauss, Hauer & Feld, L.L.P., No. 16-2435.

Respectfully submitted,

April 5, 2004
(Date)

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